

4. On information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

5. On information and belief, Apotex Corp. is a corporation organized under the laws of the State of Delaware, having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

6. Apotex Inc. and Apotex Corp. hereinafter are referred to collectively as “Apotex.”

### **JURISDICTION AND VENUE**

7. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

8. On information and belief, Apotex Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. On information and belief, Apotex Inc. directly, or through its affiliates and agents, including Apotex Corp., manufactures, markets and sells drug products throughout the United States and in this judicial district.

9. Apotex Inc. has designated William A. Rakoczy of Rakoczy Molino Mazzochi Siwik LLP, 6 West Hubbard Street, Suite 500, Chicago, Illinois 60610, as Apotex Inc.’s agent authorized to accept service of process for Apotex Inc. in this action, and has thereby consented to personal jurisdiction in this district.

10. On information and belief, Apotex Corp. directly, or indirectly, manufactures, markets and sells drug products, including generic drug products manufactured by Apotex Inc., throughout the United States and in this judicial district. On information and belief, Apotex Corp. purposefully has conducted and continues to conduct business in this judicial district.

11. Apotex has previously submitted to jurisdiction in this judicial district by filing suit in this jurisdiction and by asserting counterclaims in other civil actions, including patent cases.

12. This Court has personal jurisdiction over Apotex by virtue of, *inter alia*, the above-mentioned facts.

13. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b).

**CLAIM FOR RELIEF – PATENT INFRINGEMENT**

14. Plaintiff NPC holds an approved new drug application (“NDA”) NDA No. 50-791 for Myfortic7 delayed-release tablets (180 mg and 360 mg), which tablets contain the active ingredient mycophenolic acid, in its sodium salt form, mycophenolate sodium. Myfortic7 tablets were approved by the FDA in 2004 for the prophylaxis (or prevention) of organ rejection in patients receiving allogeneic renal transplants, administered in combination with cyclosporine and corticosteroids. NPC markets Myfortic7 delayed-release tablets (180 mg and 360 mg) in the United States.

15. Myfortic7 delayed-release tablets are an enteric formulation of mycophenolate sodium that delivers the active moiety mycophenolic acid. Mycophenolic acid is an immunosuppressant agent. As the sodium salt, mycophenolic acid can be chemically designated as (E)-6-(4-hydroxy-6-methoxy-7-methyl-3-oxo-1,3-dihydroisobenzofuran-5-yl)-4-methylhex-4-enoic acid sodium salt.

16. Novartis AG is the owner of United States Letters Patent No. 6,025,391 (“the ‘391 patent”). The ‘391 patent was duly and legally issued on February 15, 2000. A true copy of the ‘391 patent is attached hereto as Exhibit A.

17. The ‘391 patent claims, *inter alia*, pharmaceutical compositions, containing a mycophenolate salt, adapted to prevent release of the mycophenolic salt in the stomach and to release the mycophenolate salt in the upper part of the intestinal tract. It also claims, *inter alia*,

pharmaceutical compositions containing an enteric coated pharmaceutically acceptable mycophenolate salt. The '391 patent also claims, *inter alia*, methods of immunosuppressing a subject in need of immunosuppression, by administering a therapeutically effective amount of enteric coated pharmaceutically acceptable mycophenolate salt.

18. The '391 patent was assigned by the inventors to Novartis AG.

19. Novartis AG is the owner of United States Letters Patent No. 6,172,107 ("the '107 patent"). The '107 patent was duly and legally issued on January 9, 2001. A true copy of the '107 patent is attached hereto as Exhibit B.

20. The '107 patent claims, *inter alia*, pharmaceutical compositions, containing a mycophenolate salt, formulated to disintegrate selectively in the intestinal tract to release mycophenolate there. It also claims, *inter alia*, pharmaceutical compositions containing an enteric coating that are suitable as an immunosuppressant medicament. The '107 patent also claims, *inter alia*, methods of immunosuppressing a subject in need of immunosuppression, by administering a therapeutically effective amount of a composition formulated to disintegrate selectively in the intestinal tract to release mycophenolate there.

21. The '107 patent was assigned by the inventors to Novartis AG.

22. Novartis AG is the owner of United States Letters Patent No. 6,306,900 ("the '900 patent"). The '900 patent was duly and legally issued on October 23, 2001. A true copy of the '900 patent is attached hereto as Exhibit C.

23. The '900 patent claims, *inter alia*, pharmaceutical compositions, containing a mycophenolate salt, adapted to prevent release of mycophenolate in the stomach.

24. The '900 patent was assigned by the inventors to Novartis AG.

25. On information and belief, Apotex submitted to the FDA an abbreviated new drug application (“ANDA”) under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic Myfortic<sup>7</sup> delayed-release tablets 180 mg and 360 mg (hereinafter “Apotex’s Products”).

26. On information and belief, Apotex submitted its ANDA to the FDA on or about June 4, 2009.

27. On information and belief, Apotex submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex’s Products before the expiration of the ‘391, ‘107 and ‘900 patents.

28. By filing the ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex’s Products before the expiration of the ‘391, ‘107 and ‘900 patents, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of Apotex’s Products for which Apotex seeks approval will also infringe one or more claims of the ‘391, ‘107 and ‘900 patents.

29. Apotex’s Products, if approved, will be administered to human patients in an amount effective to immunosuppress those patients, which administration constitutes direct infringement of the ‘391 and ‘107 patents. This will occur at Apotex’s active behest, and with its specific intent, knowledge and encouragement. On information and belief, Apotex will actively induce, encourage, aid and abet this administration with the knowledge that it is in contravention of Plaintiffs’ rights under the ‘391 and ‘107 patents.

30. Apotex made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) (“Paragraph IV certification”) that, in its opinion and to the best of its knowledge,

the '391, '107 and '900 patents are invalid and alleges that some, but not all of the claims of each of the three patents are not infringed. Apotex did not allege unenforceability of any of the '391, '107 and '900 patents in its Paragraph IV certification.

31. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval of the aforementioned ANDA relating to Apotex's Products be a date which is not earlier than the later of the April 10, 2017 expiration dates of the '391, '107 and '900 patents or any later date of exclusivity to which Plaintiffs are or become entitled. Further, Plaintiffs are entitled to an award of damages for any commercial sale or use of Apotex's Products, and any act committed by Apotex with respect to the subject matter claimed in the '391, '107 and '900 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

32. On information and belief, when Apotex filed its ANDA, it was aware of the '391, '107 and '900 patents, and that the filing of its ANDA with the request for its approval prior to the expiration of that patent was an act of infringement.

33. This is an exceptional case, and Plaintiffs are entitled to an award of reasonable attorneys fees under 35 U.S.C. § 285.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Apotex has infringed one or more claims of the '391, '107 and '900 patents by filing the aforesaid ANDA relating to Apotex's Products;

B. A permanent injunction restraining and enjoining Apotex and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the

commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Apotex's Products;

C. An Order that the effective date of any approval of the aforementioned ANDA relating to Apotex's Products be a date which is not earlier than the later of the expiration of the right of exclusivity under the '391, '107 and '900 patents, or any later right of exclusivity to which Plaintiffs are or become entitled;

D. Damages from Apotex for any commercial activity constituting infringement of the '391, '107 and '900 patents;

E. A finding that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs are entitled to the costs and reasonable attorney fees in this action; and

F. Such other and further relief as the Court may deem just and proper.

Dated: November 4, 2009

/s/ David C. Van Dyke

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